

REMARKS

Claims 39-44 are pending in the present application, and new claims 45-58 are added. By this amendment, Applicants have canceled claims 1-38 without prejudice or disclaimer. Applicants reserve the right to pursue these canceled claims in a continuation or divisional application. Applicants have amended claims 39 and 40 to recite the term "non-naturally occurring." This amendment is supported at least by pages 15-16 and 19-26 and Examples 1-4 of the specification.

In addition, Applicants have added new claims 45-58. Claims 45-49 are supported at least by page 9, lines 12-18; from page 13, line 24, to page 14, line 11; from page 15, line 1, to page 16, line 25; and Figure 1 of the specification. Claims 50-55 are supported at least by page 9, lines 19-25; page 14, lines 13-34; from page 15, line 1, to page 16, line 25; and Figure 2 of the specification. Claims 56-58 are supported at least by page 10, lines 3-24 and from page 19, line 14, to page 21, line 26 of the specification, and by original claims 29-38.

The amendments to the claims do not introduce new matter. Accordingly, Applicants respectfully request entry of these amendments.

Rejection Under 35 U.S.C. § 101

On page 2, the Office Action rejects claims 39-40 and 43-44 as allegedly being directed to non-statutory subject matter. Applicants respectfully traverse the rejection.

Applicants have amended claims 39 and 40 to recite the phrase "non-naturally occurring." Applicants believe that this amendment obviates the Examiner's rejection of claims 39 and 40.

The Office Action contends that claims 43-44 read on a transgenic human and that a transgenic human is not a patentable subject matter. Without agreeing or disagreeing whether a transgenic human is a patentable subject matter, Applicants respectfully submit that claims 43-44 are directed to genetically-engineered cells, not transgenic humans. The fact that a claimed cell can be included in a human body does not render the claimed cell non-statutory subject matter. Otherwise, any drug or implantable medical device, which has long been deemed patentable subject matter, would be considered unpatentable because they read on a human, whether transgenic or not, when they are taken or implanted into a human.

Based on the above reasons, Applicants respectfully submit that claims 39-40 and 43-44, as currently presented, are directed to patentable subject matter. Withdrawal of the rejection is, therefore, respectfully requested.

Rejection Under 35 U.S.C. § 112, First Paragraph

On pages 3-6, the Office Action rejects claims 39-44 for allegedly not being enabled. Applicants respectfully traverse this rejection.

The Office Action contends that polynucleotides with at least 90% sequence identity to SEQ ID NOs: 3, 4, 7 or 8, as recited in claims 39-44, are "overly broad since insufficient guidance is provided as to which of the myriad of variant nucleic acids encode polypeptides which will retain the characteristics of SEQ ID NO: 3, 4, 7, 8." However, Example 3 of the specification provides detailed methods for evaluating interactions between two polypeptides using a yeast two-hybrid screen. Applicants, accordingly, respectfully submit that one of ordinary skill in the art would know that any given variant of SEQ ID NOs: 3, 4, 7 or 8 can be readily assessed for its function using this method. The Office Action has failed to present any specific mutation or amino acid change that would require undue experimentation to determine its effect on the function of variants of SEQ ID NOs: 3, 4, 7 or 8. Moreover, the methods described in Example 3 do not involve any unpredictable arts. Accordingly, Applicants respectfully submit that the present application teaches how to make and use a claimed variant without undue experimentation and that the Office Action has failed to establish a *prima facie* case of lack of enablement. Reconsideration of the rejection is, therefore, respectfully requested.

On pages 6-7, the Office Action rejects claims 39-44 for allegedly not satisfying the written description requirement. Applicants respectfully traverse this rejection also.

The Office Action argues that the "specification and claim[s] do not indicate what distinguishing attributes shared by the members of the genus" (i.e., polynucleotides having at least 90% sequence identity to SEQ ID NOs: 3, 4, 7 or 8) and that the "structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure." However, from page 22, line 14, to page 23, line 11, the specification indeed provides exemplary methods for determining sequence identities. Based on these methods, the sequence identity of any given sequence, as compared to SEQ ID NOs: 3, 4, 7 or 8, can be readily determined. Therefore, a common structural feature shared by the members in the genus, without considering the doctrine of equivalents, is that all of the sequences in the genus have at least 90% sequence identity to SEQ ID NOs: 3, 4, 7 or 8. This feature distinguishes the members of the genus from other proteins based on the literal construction of the claims. The fact that the genus is highly variant does not render SEQ ID NOs: 3, 4, 7

Docket No. 31896-069100
(formerly AHP 98133 C1)
Patent

and 8 non-representative. In fact, the Office Action has failed to present any specific sequence whose sequence identity, as compared to SEQ ID NOs: 3, 4, 7 or 8, cannot be determined at the time the present application was filed. Accordingly, Applicants respectfully submit that the present application reasonably conveys to one of ordinary skill in the art that Applicants, at the time the present application was filed, had possession of all of the sequences that have at least 90% sequence identity to SEQ ID NOs: 3, 4, 7 or 8, as set forth in the claims, and that the Office Action has failed to establish a *prima facie* case of lack of written description. Therefore, withdrawal of this rejection is also respectfully requested.

Based on the foregoing, Applicants respectfully submit that claims 39-44 meet the enablement and written description requirements under 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of the § 112, first paragraph, rejections are, therefore, respectfully requested.

Rejection Under 35 U.S.C. § 102

On page 7, the Office Action rejects claims 39, 41, and 43 under 35 U.S.C. § 102(b) as allegedly being anticipated by Christie et al. (1989) (hereinafter "Christie"). Applicants respectfully traverse this rejection.

Upon review of this reference, Applicants respectfully submit that Christie fails to teach a polynucleotide encoding both a DNA-binding or transcription activation domain and SEQ ID NO: 3 or 4 or a variant thereof. Therefore, Christie fails to teach each and every element of claims 39, 41 and 43. Accordingly, Christie does not anticipate these claims. Reconsideration and withdrawal of the § 102(b) rejection are, therefore, respectfully requested.

On page 8, the Office Action rejects claims 39-44 under 35 U.S.C. § 102(b) as allegedly being anticipated by Tamkun et al. (1991) (hereinafter "Tamkun"). Applicants respectfully traverse this rejection also.

Like Christie, Tamkun fails to teach a polynucleotide encoding both a DNA-binding or transcription activation domain and SEQ ID NO: 3, 4, 7 or 8 or a variant thereof. Therefore, Tamkun fails to teach each and every element of claims 39-44. Accordingly, Applicants respectfully submit that Tamkun does not anticipate these claims. Reconsideration and withdrawal of the § 102(b) rejection are, therefore, respectfully requested.

Finally, on pages 8-9, the Office Action also rejects claims 40, 42 and 44 under 35 U.S.C. § 102(b) as allegedly being taught by Leicher et.al. (1996) (hereinafter "Leicher"). Applicants respectfully traverse this rejection.

Like Christie and Tamkun, Applicants respectfully submit that Leicher fails to teach a polynucleotide encoding both a DNA-binding or transcription activation domain and SEQ ID NO: 7 or 8 or a variant thereof. Therefore, Leicher fails to teach each and every element of claims 40, 42 and 44. Reconsideration and withdrawal of the § 102(b) rejection is, therefore, respectfully requested.

Based on all of the above reasons, Applicants respectfully submit that neither Christie, Tamkun, nor Leicher, individually or in combination, teaches the required elements in claims 39-44. Therefore, these references do not anticipate claims 39-44. Applicants respectfully also submit that the disclosures set forth in Christie, Tamkun and Leicher also fail to render the claimed subject matter obvious to one of ordinary skill in the art, and those references, whether individually or in combination, are inadequate under a 35 U.S.C. § 103 analysis also.

NOV. 11. 2004 6:51PM

NIXON PEABODY

NO. 6626 P. 12

Docket No. 31896-069100
(formerly AHP 98133 C1)
Patent

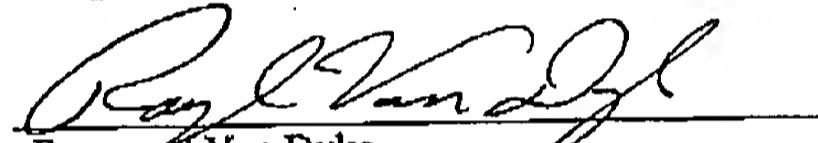
CONCLUSION

For at least the reasons set forth above, Applicants respectfully submit that this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly solicited.

Although Applicants believe that no fee is due, the Commissioner is hereby authorized to charge any payment deficiency to deposit account number 19-2380 referring to attorney docket number 031896-069100.

Should the Examiner believe that anything further is desired in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,


Raymond Van Dyke
Reg. No. 34,746

Date: November 11, 2004

Nixon Peabody LLP
Suite 900
401 9th Street, N.W.
Washington, D.C. 20004-2128
Tel: (202) 585-8250
Fax: (202) 585-8080